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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,157	06/16/2006	Viktor Menart	33581-US-PCT	5099
7590 11/24/2009				
Mark S. Graham, Esq. LUEDEKA, NEELY & GRAHAM, P.C. P.O. Box 1871 Knoxville, TN 37901				
EXAMINER				
WOODWARD, CHERIE MICHELLE				
ART UNIT		PAPER NUMBER		
1647				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/583,157

**Applicant(s)**

MENART ET AL.

**Examiner**

CHERIE M. WOODWARD

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 18 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-12 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) 14-16 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/GS-08)  
Paper No(s)/Mail Date 6/18/2009
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Formal Matters***

1. Applicant's Response filed 6/18/2009 is acknowledged and entered. Claims 1-12 and 14-16 are pending. Claims 14-16 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Claims 1-12 are under examination as they are drawn to the species of G-CSF.

### ***Information Disclosure Statement***

2. The information disclosure statement (IDS) submitted on 6/18/2009 has been considered by the examiner. A signed copy is attached hereto.

### ***Response to Arguments***

#### ***Rejections Withdrawn***

3. The provisional rejection of claims 1-4 and 8-10 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3, 8, and 9 of copending Application No. 10/577,285, is withdrawn in light of the Terminal Disclaimer filed 6/18/2009. It is noted that Applicant's arguments related to 35 USC 103(c) are not applicable to double patenting rejections because double patenting rejections require the same assignee or at least one inventor in common (see Remarks, p. 7).

4. The provisional rejection of claim 12 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-7, and 26 of copending Application No. 10/522,826, is withdrawn in light of the Terminal Disclaimer filed 6/18/2009. It is noted that Applicant's arguments related to 35 USC 103(c) are not applicable to double patenting rejections because double patenting rejections require the same assignee or at least one inventor in common (see Remarks, p. 7).

### ***Rejections Maintained***

#### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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(c) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1, 2, 5, 10, and 12 remain rejected under 35 U.S.C. 102(b) as being anticipated by Miyazawa et al (US Patent 5,500,416, 19 March 1996) (cited in Applicant's IDS of 6/16/2006), for the reasons of record and the reasons set forth herein.

Applicant argues that Miyazawa does not teach the use of NDSBs as part of a composition containing an active pharmaceutical agent (Remarks, p. 6). Applicant distinguishes NDSB from other surfactant or detergent sulfobetaines (Remarks, pp. 5 and 6).

Applicant's arguments have been fully considered, but they are not persuasive. As stated of record, Miyazawa et al., do, in fact, teach compositions comprising active pharmaceutical ingredients, including pharmaceutically acceptable excipients, and non-detergent sulfobetaine (NDSB) (column 2, lines 61 to column 3, line 32; column 5, line 47 to column 7, line 58) (see also claims 1, 6, 7, and 8) (compare instant claims 1, 2, 5, 10, and 12). Examples of various NDSBs are taught at column 3, lines 22-32; column 4, lines 32-46; and claims 7 and 9.

7. Claims 1-6 and 8-12 remain rejected under 35 U.S.C. 102(c) as being anticipated by Menart et al., WO 2004/015124 (published 19 February 2004, priority to 11 June 2003; published in English and designating the US), for the reasons of record and the reasons set forth herein.

Applicant argues that the effective date of the Menart et al., reference has been overcome by the submission of an English language translation because the Menart et al., reference was published on 19 February 2004 (Remarks, p. 6).

Applicant's arguments and submission of the foreign translation document are acknowledged, but they are insufficient to overcome the instant rejection of record. The Menart et al., has a publication date of 19 February 2004, but it claims priority to at least its filing date of 11 June 2003. Because the Menart et al., reference was filed in English and designates the US, it is applicable as prior art under 35 USC 102(c) as of its filing date of 11 June 2003, which is prior to the earliest benefit of the instant Application even with the foreign translation (claiming priority to 12/23/2003). Additionally, the inventive entity is not the same between the Menart et al., reference and the instant application, even though the reference shares two common inventors and the same assignee. Accordingly, the Menart et al., reference still qualifies as prior art under 35 USC 102(c). See MPEP 706.02(f)(1) and flowchart showing 35 USC

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102(e) dates for WIPO publications of International Applications. The 35 USC 102(e) date is the international filing date. The foreign priority claims of the Menart et al., reference have not been considered by the examiner.

*Claim Rejections - 35 USC § 103*

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claim 7 remains rejected in addition to claims 1-6 and 8-12 under 35 U.S.C. 103(a) as being unpatentable over Menart et al., WO 2004/015124 (published 19 February 2004, priority to 11 June 2003; published in English and designating the US) and Vuillard et al., (Biochem J. 1995;305:337-343), for the reasons of record and the reasons set forth herein.

Applicant argues that the effective date of the Menart et al., reference has been overcome by the submission of an English language translation because the Menart et al., reference was published on 19 February 2004 (Remarks, p. 7).

Applicant's arguments and submission of the foreign translation document are acknowledged noted, but they are insufficient to overcome the instant rejection of record. The Menart et al., has a publication date of 19 February 2004, but it claims priority to at least its filing date of 11 June 2003. Because the Menart et al., reference was filed in English and designates the US, it is applicable as prior art under 35 USC 103(a) as a prior art document with a 102(c) effective filing date of 11 June 2003, which is prior to the earliest benefit of the instant Application even with the foreign translation (claiming priority to 12/23/2003). Additionally, the inventive entity is not the same between the Menart et al., reference and the instant application, even though the reference shares two common inventors and the same assignee. Accordingly, the Menart et al., reference still qualifies as prior art under 35 USC 102(c). See MPEP 706.02(f)(1) and flowchart showing 35 USC 102(c) dates for WIPO publications of International Applications. The 35 USC 102(c) date is the international filing date. The foreign priority claims of the Menart et al., reference have not been considered by the examiner.

### ***Conclusion***

NO CLAIM IS ALLOWED.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHERIE M. WOODWARD whose telephone number is (571)272-3329. The examiner can normally be reached on Monday - Friday 9:30am-6:00pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)? If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Cherie M. Woodward/  
Primary Examiner, Art Unit 1647